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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,759	08/25/2003	Kevin J. Brodbeck	ARC 2882 N1 (3139-6225.1U	3721

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,759	BRODBECK ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *15 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-28 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14,16-28 and 30-35* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are currently pending.

Election/Restrictions

Applicant's election without traverse of the species "human growth hormone" and "benzyl benzoate" in the reply filed on 1/26/07 is acknowledged. Claims 15 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/26/07. The previous election of the species "C_{16}-C_{24} fatty acid esters" in the 10/31/06 reply is noted; this election reads on claims 3, 4, and 18.

Examination on the merits will commence at this time on claims 1-14, 16-28, and 30-35 as they read on the elected species where appropriate.

Priority

The amendment to the specification received 10/31/06 designating application 09/585,590 as a "utility conversion" of a provisional application is noted. It is noted for the record that the '590 application is actually a "non-provisional application" (*i.e.*, a filing under 35 U.S.C. § 111(a)) of said provisional application; the term "utility conversion" implies that the '590 application claims benefit of a design or plant patent in some manner. See 37 C.F.R. 1.78 (a) (2) (iii). Correction in the form of an amendment to the specification is requested to clarify the chain of priority.

Specification

The disclosure is objected to because of the following informalities: It refers to application serial number 08/993,208, which issued as U.S. Patent 6,130,200 on 10/10/2000. The status of this and all U.S. patent applications referenced in the specification should be updated.

Drawings

Figure 1 is an informal drawing that is sufficient for examination purposes, but at the time of allowance, a formal drawing will be required to substitute for handwritten Figure 1.

Claim Objections

Claim 9 is objected to because of the following informalities: This claim does not comply with standard English. The word "are" at line 2 should be replaced with "is." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Baichwal et al. (1997, U.S. Patent 5,662,933 (5/25/05 IDS) taken in light of information from rxlist.com (reference U; http://www.rxlist.com/cgi/generic/comvent.htm, accessed online 4/2/07).

Baichwal et al. teach a pharmaceutical composition comprising granulated albuterol sulfate (an active agent; column 4, lines 10-13) and carboxymethylcellulose (a hydrophobic agent with low water solubility; column 3, lines 1-12) in a gel carrier comprising xanthan gum and locust bean gum (Abstract; Examples 1-2; column 13, line 50, through column 14, line 57). Xanthan gum and locust bean gum are biocompatible (column 6, lines 46-54). Information from rxlist.com is cited as evidence that albuterol sulfate is inherently water-soluble (page 2, line 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 16-28, and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (2000, U.S. Patent 6,130,200; 5/25/05 IDS) taken in view of Yamagata et al. (1997, U.S. Patent 5,628,993; 5/25/05 IDS) and Ayer et al. (2000, U.S. Patent 6,096,339; reference A). Brodbeck is prior art under 35 U.S.C. §

102(e) because the application was filed in the U.S. before the current application and the inventive entity differs from that of the instant application; see M.P.E.P. § 2136.04.

Brodbeck teaches a sustained-release pharmaceutical composition comprising particles of spray-dried, lyophilized human growth hormone (HGH, an active agent that is a water-soluble polypeptide) and zinc acetate (a solubility modulator) suspended in a gel of poly-(D,L-lactide-co-glycolide) (PLGA, a biocompatible gel carrier) and benzyl benzoate (a solvent) (Example 2; column 23, line 45, through column 26, line 16). Brodbeck teaches that the solubility modulator, *i.e.*, an agent that alters the solubility of the active agent with reference to the polymer solvent or water (column 10, lines 17-29), may be a lipid or oil (column 15, lines 39-43, especially line 42). Brodbeck teaches making this composition by mixing a biocompatible polymer with the benzoic acid solvent to form a viscous gel, dispersing an active agent associated with a solubility modulator into the gel, and adding further components as desired (column 6, line 62, through column 7, line 7); specifically, Brodbeck teaches spray-drying a mixture of HGH and zinc acetate to yield 2-100 micron particles (column 23, line 50, through column 24, line 27).

Brodbeck does not exemplify a composition in which the solubility modulator is hydrophobic, specifically a fatty acid ester, more specifically a C_{16}-C_{24} fatty acid ester, more specifically a mixture of stearic acid and palmitic acid in particular proportions. Brodbeck does not teach making the particles comprising the active agent by crushing a compressed mass of active agent.

Yamagata teaches a sustained-release pharmaceutical composition comprising powdered particles comprising interferon-α (a water-soluble polypeptide) dispersed in a matrix of tetraglycerol dipalmitate (a fatty acid ester of palmitic acid) or tetraglycerol distearate (a fatty acid ester of stearic acid) (Examples 1-3; column 8, lines 3-37; column 6, lines 21-38). The composition of Yamagata may comprise hormones (column 4, lines 25-32). Yamagata teaches that the composition may comprise more than one fatty acid diester (column 5, lines 32-34; column 6, lines 4-5) and that the amount of each fatty acid diester in the composition may be optimized (column 6, lines 39-45).

Ayer teaches that particles comprising active agents that are included in controlled-release pharmaceutical compositions may be made by spray-drying or crushing, among other methods (column 13, lines 15-21).

A person of ordinary skill in the art would have had a reasonable expectation of success in substituting the palmitic acid and stearic acid diesters of Yamagata for the zinc acetate as a solubility modulator in the composition of Brodbeck because Brodbeck suggests that lipids and oils may act as solubility modulators. The skilled artisan would have been motivated to substitute the diesters of Yamagata for the zinc acetate in the composition of Brodbeck because Yamagata teaches that the diesters protect physiologically active peptides from hydrolysis and preserve their activity, allowing for sustained release of active polypeptide (column 2, lines 14-19).

The selection of the amount of palmitic acid diester and stearic acid diester to include in the composition of Brodbeck would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Yamagata

teaches that the amount of a given diester in a sustained-release composition is widely optimizable (column 6, lines 39-45). A holding of obviousness over the cited claims is therefore clearly required.

The selection of the method used to make particles comprising HGH and the solubility modulator in the method of Brodbeck would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Ayer teaches that spray-drying and crushing are art-accepted equivalents for yielding particles of dried pharmaceuticals, including polypeptides (column 11, lines 37-47, especially line 41). A holding of obviousness over the cited claims is therefore clearly required.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute various amounts of palmitic acid diester and stearic acid diester for the zinc acetate in the composition of Brodbeck and to substitute crushing for spray-drying in the method of procuction because Yamagata teaches that fatty acid diesters are solubility modulators, because Brodbeck suggests that the solubility modulator may be a lipid, and because Ayer establishes the art-recognized equivalence of crushing and spray-drying for producing particles of pharmaceutically active agents.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

No claims are allowed. No claims are free of the art.

Applicant is requested to specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart